**HEALTH** 

## In New Calculus on Smoking, It's Health Gained vs. Pleasure Lost

By SABRINA TAVERNISE AUG. 6, 2014



A cost-benefit analysis embedded in new regulations that would extend the F.D.A.'s authority to electronic cigarettes and other tobacco products is causing consternation in public health circles.

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WASHINGTON — Rarely has the concept of happiness caused so much consternation in public health circles.

Buried deep in the federal government's voluminous <u>new tobacco regulations</u> is a little-known cost-benefit calculation that

public health experts see as potentially poisonous: the happiness quotient. It assumes that the benefits from reducing smoking — fewer early deaths and diseases of the lungs and heart — have to be discounted by 70 percent to offset the loss in pleasure that smokers suffer when they give up their habit.

Experts say that calculation wipes out most of the economic benefits from the regulations and could make them far more vulnerable to legal challenges from the tobacco industry. And it could have a perverse effect, experts said. The more successful regulators are at reducing smoking, the more it hurts them in the final economic accounting.

"This threatens the F.D.A.'s ability to take strong actions against tobacco," Frank J. Chaloupka, an economist at the University of Illinois at Chicago, said of the Food and Drug Administration. "If they can't demonstrate that there is a significant economic benefit to doing it, then it makes their job much harder."

On Wednesday, Professor Chaloupka and other prominent economists, including a Nobel Prize winner, publicly took issue with the analysis. In a paper submitted to the F.D.A. as the period for public comment on the regulations neared its end on Friday, the group said the happiness quotient was way too high and should be changed before the regulations take effect.

"There's reason to believe that number is much too big," said Jonathan Gruber, an economist at the Massachusetts Institute of Technology who was an author of the paper. In his view, the agency's analysis cited his past work erroneously.

The idea of lost happiness is new for health regulation. But it has surfaced as part of a longstanding requirement — first codified under President Bill Clinton — that every set of federal regulations with more than a \$100 million effect on the economy needs an analysis to prevent the adoption of regulations with high costs and low benefits.

The cost-benefit analysis is embedded in a proposal from April that would extend the F.D.A.'s authority, for the first time, to electronic cigarettes and other tobacco products such as cigars and pipe tobacco, with potentially large consequences for the multibillion-dollar tobacco industry.

The F.D.A. released a statement on Wednesday detailing the economics behind its analysis, but the explanation did not address the central assertion made by the economists. An F.D.A. spokeswoman, Jennifer Haliski, said that there was "still a great deal of uncertainty" surrounding the calculation, and that the agency was helping fund research to explore the issue. She emphasized that the whole purpose of a public comment period was to get the best information before the new regulations became final. "Comments are encouraged and all will be considered," she said.

If the formula for assessing costs and benefits remains unchanged in the final version of the regulations, it could set a dangerous precedent that would constrain public-policy making for years to come, experts and advocates warned.

"This is the single biggest obstacle facing the F.D.A. in executing the job Congress gave it," said Matthew L. Myers, president of the Campaign for Tobacco-Free Kids, an advocacy group. "There's no way the F.D.A. can do its job if this is applied."

This approach to cost-benefit analysis could also have broader implications for regulations of the food and beverage industries, which could likewise point to lost pleasure from consumption of sugar, salt or other substances regulators seek to limit.

"If this is a beachhead into this kind of analysis, that should be setting off alarms," said Lisa Heinzerling, a law professor at Georgetown University and an author of "Priceless: On Knowing the Price of Everything and the Value of Nothing," a critique of cost-benefit analysis.

The economists' assessment of the agency's approach is part of a flood of public comments — more than 69,000 as of Wednesday — submitted to the F.D.A. on the tobacco regulations. The rules are supposed to become final by next summer, and experts anticipate that legal challenges will soon follow.

The economists speaking out on Wednesday said a basic assumption consistent with traditional economic theory lay at the heart of the federal government's miscalculation on the costs and benefits of the regulations: that most people were rational, well-informed market participants making decisions they would not later regret.

But smokers, they said, were different. A vast majority began smoking before age 18, when judgment is impaired. And many want to quit, but are addicted, and forgo the long-term satisfaction of better health for short-term pleasure.

"It would be ridiculous to suggest that a 16-year-old kid who has no idea what addiction means and feels immortal is a rational decision-maker when it comes to smoking," said Kenneth E. Warner, one of the paper's authors and a professor of public health at the University of Michigan.

Pleasure was not the only problem with the F.D.A.'s economic analysis, the economists said. For example, it did not count the benefits to nonsmokers of less secondhand smoke, or of reductions in infant mortality were fewer pregnant women to smoke, they said.

The only previous application of the happiness loss by the F.D.A. — to the proposal of graphic warning labels on cigarette packaging — went largely unnoticed, but the current one is drawing attention because of

just how much the lost happiness counts.

The outside economists began their analysis of the regulations for the graphic warning labels, and said their conclusions applied directly to the new tobacco rules as well. They said the F.D.A.'s analysis — which was conducted by the agency's own economists, said Ms. Haliski, the F.D.A. spokeswoman — relied on standard economic theory that was simply not appropriate in these circumstances, and they urged the agency to reconsider its calculations.

"If you have an analysis that's strongly biased to find fewer net benefits than realistically should be there, when you get into court cases and political challenges, the regulation is severely weakened," Professor Warner said.

The aspect that dealt with lost pleasure was referred to as a "welfare gain ratio," and was rendered in technical language starting on Page 52 of the agency's "regulatory impact document."

"These are not dumb people — this is hard stuff," Professor Gruber said of the F.D.A. economists. "But we got an eminent group of people together and we came up with a different conclusion."

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